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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,570	09/27/2001	Toshiya Kai	NPR-085	8923

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,570	KAI ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-9,11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-9,11 and 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Prosecution and Amendments/Remarks received on May 3, 2004 is acknowledged. Claims **1, 4, 7-9, 11, 13, 14-23** are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 7-9, 11, 13, 14-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,407,070 and 6,489,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim similar subject matter.

Instant applicant claims a solid preparation with tow different composition: 1) sodium chloride cores coated with electrolytes 2) a glucose core coated with a different or same sugar and 3) an acid. The claim recites a particle size of 330 to 1700 microns. Claim 7 recites the preparation containing sodium bicarbonate.

US '070 patent recites a solid dialysate containing a granular agent A of a core sodium chloride particle coated with electrolytes, and acid. Claim 2 recites that the glucose is contained

in granular agent A. Granular B contains sodium bicarbonate. Claim 5 recites spray drying the composition to yield the product.

US '301 recites a solid dialysate preparation containing an electrolyte, a solid organic acid, and glucose. The composition is in the form of layers wherein sodium chloride is the core particle, followed by a layer of sodium acetate, and other electrolytes. The electrolyte particle is coated with an organic acid layer, a glucose layer, and a sodium bicarbonate layer. The powder diameter is 0.03 to 0.5 mm.

The instant application and US patent ('070) are obvious modifications of each other since instant application is in essence claiming a narrower scope of US patent's granular agent A. Instant application since recites all the components of granular A with a particle size limitation. Therefore, the instant claims fall within the scope of granular A's composition recited in US patent.

The instant application and US patent ('301) are obvious modifications of each other. Instant application recites the same components as US patent, i.e. a sodium chloride core with a coating layer of electrolytes, glucose, acid, and sodium bicarbonate. However, the instant application does not specify the structural formation of glucose, acid, and sodium bicarbonate in the composition. US patent recites the same components in a coated/layered structure including the glucose, acid, and sodium bicarbonate. Thus, US patent's scope falls into instant application's generic scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7-9, 11, 13, 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims recite a solid preparation with three different composition: 1) sodium chloride cores coated with electrolytes 2) a glucose core coated with a different or same sugar 3) an acid. It is unclear if applicant's intent is that the product, i.e. the dialysis product, contains within it three separate and individual compositions of 1, 2, and 3 **or** if applicant intends that the product contains three different components, sodium chloride core coated with electrolytes, glucose coated with a sugar, and an acid in a combined to form the product. The claims will accordingly be rejected according to both interpretations. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-9,11, 13, and 14-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0399918.

EP discloses a powder dialysis preparation containing two compositions. The first composition contains 2188.7 parts sodium chloride particles with a coating layer of 35.6 parts magnesium chloride hexahydrate, 77.2 parts calcium monohydrate, 215.2 parts sodium acetate trihydrate, and acetic acid with instant average particle diameter of 32-48 mesh. See example 1. The second composition contains 525 parts glucose and 750 parts sodium hydrogen carbonate

with instant average particle diameter of 12-32 mesh. See example 3. Examples and claims show that glucose particles are added to the electrolyte composition. See page 4 and 8-9. In example 2, sodium chloride is sprayed with an aqueous solution of the instant electrolytes are sprayed. EP discloses the first composition has a particle range of 10-200 mesh (2000 microns to 75 microns) and preferably 14-100 mesh (1400 microns to 150 microns). See page 9, lines 39-40. The first composition is made by dissolving the solid electrolytes other than sodium chloride, spraying the resultant aqueous solution into a fluidize bed formed of sodium chloride. See page 6, line 56 to page 7, line 1. The second composition has a particle range of 10-100 mesh (2000 microns to 150 microns) and preferably 12-100 mesh (1700 micron to 150 microns). See page 7, lines 8-10. The acid taught is acetic acid. See abstract. Lastly, example 8 discloses an alternative embodiment of the invention wherein an aqueous solution is obtained by dissolving potassium chloride, magnesium chloride, calcium chloride, and sodium acetate in water. Then sodium chloride and glucose are sprayed with the aqueous solution to increase the weight of the particles and acid is added and mixed. The average particle diameter is 40-80 mesh (425 microns to 180 microns). Note that it is the examiner's position that once the sodium chloride is sprayed with the electrolytes it makes the "first composition" and the glucose sprayed with the electrolytes makes the "second composition." The instant claims language does not exclude the glucose particles from having additional coatings.

Response to Arguments

Applicant argues that the instant solid preparation corresponds to EP's first composition and does not contain sodium bicarbonate. Further, it is argued that the instant preparation is mixed later with sodium bicarbonate.

Firstly, this argument is confusing since applicant's position prior to this response has been that the glucose, the electrolytes, and acid are separate compositions. However, presently applicant is claiming that the instant composition is one composition akin to EP's first composition. In accordance to this argument, the examiner rejects the instant claim over example 8 of EP wherein EP discloses a first composition containing sodium chloride sprayed with instant electrolytes and glucose sprayed with instant electrolytes and then mixed with acid. The particle range falls within the instant particle range. This composition does not contain sodium bicarbonate.

Applicant argues that the first composition disclosed do not teach a sodium chloride core having a coating layer of electrolytes.

The examiner points to page 6, line 56 to page 7, line 1 wherein the first composition is made by dissolving the solid electrolytes other than sodium chloride, spraying the resultant aqueous solution into a fluidize bed formed of sodium chloride. The examiner notes example 1 does not disclose the sodium chloride as a core particle, however this is an alternative embodiment for making the first composition. Example 2 discloses the instant process.

Applicant argues that in the second composition the glucose is not a core particle covered with a coating layer of the same or different sugar.

Again the examiner points out that a core sugar particle coated with the same sugar yields the same particle and in determining patentability of claims directed to a product, the product is assessed for patentability and not the process. The examiner suggest overcoming this by removing the limitation wherein the core glucose is coated by the same sugar and amend the claims to recite wherein the core glucose is coated by a different sugar. Further, the claim

language is open and the scope does not exclude an additional coating such as sodium bicarbonate for the glucose particles. Therefore, the scope allows for a sodium carbonate coating to provide the instant particle size. To overcome this, the examiner suggests amending the claims to exclude sodium bicarbonate provided applicant has support for such an amendment.

Applicant argues that EP '918 does not teach a first composition with the instant size and the second composition with the instant particle size. Applicant argues that glucose has a particle diameter of 180 microns and not instant particle size. Therefore, a homogenous mixture is not produced.

The examiner points out that applicant claims that instant invention yields a homogenous mixture because both compositions have the same particle size. Firstly, it is pointed out that EP discloses similar ranges for the first and second composition encompass the instant range. The first composition is made by dissolving the solid electrolytes other than sodium chloride, spraying the resultant aqueous solution into a fluidize bed formed of sodium chloride. See page 6, line 56 to page 7, line 1. The second composition has a particle range of 10-100 mesh (2000 microns to 150 microns) and preferably 12-100 mesh (1700 micron to 150 microns). See page 7, lines 8-10. Secondly, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In instant composition, applicant only claims that the first composition has a particle range of 300 to 1700 microns and the second composition has a particle range of 300 to 1700 microns. However, applicant claims do not recite that the

particle range of both composition are the same. Thus, the claim as written allows for the first composition to have a different particle size within the instant range then the second particle. For instance, the first composition may have a article range of 500 microns and the second composition may have a particle range of 1000 microns. If applicant has support, the examiner suggests that the applicant amends the claims to recite that the first and second composition have the same particle size to provide for a homogenous mixture.

Applicant argues that example 2 does not contain glucose.

This argument is confusing since the critical aspect of the instant invention as argued is that the first composition does not contain glucose to cause instability to the composition. Secondly, the examiner points out that the example pertains to the first composition and instant first composition does not have glucose either.

Applicant argues that EP does not teach or suggest the separation of glucose from the electrolytes to prevent decomposition and coloring.

The examiner points out that EP does in fact disclose two separate composition, one containing the electrolytes and the other containing glucose. The prior art does have to show all state all the results obtainable by the disclosed process of having separate compositions.

Applicant notes that claims 8-9 are product-by-process claims but argue that the process comprises specific steps that do not include sodium bicarbonate. Thus, the claim exclude sodium bicarbonate. Applicant argues that the step requires that the glucose is coated by a same or different sugar which the prior art does not teach.

The examiner points out that the claims are product-by-process wherein patentability is based on the product itself and not the process in which it is made. Note MPEP section 2113,

which states "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Thus, it is pointed out that if one were to coat a sugar particle with the same sugar, it is the **same product**. The entire claim is directed to a product done by a particular process. Only if the process yields a different product, is the process given weight. In instant case, it does not. The use of "comprising" claim language allows for the additional step of adding sodium carbonate. Furthermore, example 8 teaches a composition without sodium carbonate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 7-9, 11, 13, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama et al (5540842) in view of Jonsson et al (4,784,495).

Aoyama discloses a dialysis powder. The powder contains 823.69 kg NaCI particles coated with instant electrolytes (26.53 potassium chloride, 36.63 kg of calcium chloride, and 21.71 kg of magnesium chloride) (1). Further, 17 liters of water and 70.07kg sodium acetate was added. See abstract, column 3, lines 35-37, and examples. Then 213. 55 kg glucose (2) (optional) is added separately. See column 5, lines 20-23 and example 3. Lastly, acetic acid (3) is added to the particles (column 5, lines 15-19). Aoyama teaches the separate use of sodium carbonate with the powder mixture. Particle sizes are taught in Table 9. The majority of the particles are 30mesh (600 microns).

Note it is the examiner's position that a sugar particle coated with the same sugar is in essence the core sugar particles, therefore Aoyama's glucose reads on instant claims. In regards to the product-by-process claims determination of patentability is based on the product itself and the patentability of a product does not depend on its method of production. If the product is same or obvious to that of the prior art as seen in instant case, then the claim is unpatentable even though it is made by a different process.

Although Aoyama teaches particle sizes, the reference does not specify the particle size of each component 1 and 2.

Jonsson et al teach a system for preparing a fluid intended by mixing at least one powder with water for medical procedures such as kidney dialysis. See abstract and column 1, lines 30-34. The reference teaches that in order to obtain an even flow of fluid throughout the powder concentrate column and thus a uniform solution of powder in the fluid, there is a preferable

minimum particle size for the concentrate. For many materials, it has been found that the particle size should be at least 100 microns and preferably larger than 150 microns. A minor blending of smaller particles in acceptable. For example, a suitable mixture is between 130 microns to 500 microns. See column 12, lines 4-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Aoyama et al and Jonsson et al and manipulate the particle size of each component in the formulation. One would be motivated to do so since Jonsson et al states that there is a preferable minimum for powder preparations in dialysis and teaches a range of 13 to 500 microns is acceptable to make a free flowing powder, which encompasses instant range. Furthermore, the manipulation of particle sizes encompassed by the prior art does not provide patentability since this is part of routine experimentation unless the applicant provides unexpected results for said particle size.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER